

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 3 is objected to because of the following informalities: Line 2 of claim 3 reads “2and” and should be changed to “and”. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3 and 9-11 provide for the use of the method of claim 3, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 3 and 9-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3 and 5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni et al. (US 5191896) in view of Demand (US 4759712) and Laudadio (US 4653507).

- Regarding claim 1, Gafni teaches a method of measuring sensory threshold which is used in the determination of sensory disorders in which a device is provided to measure thermal sensitivity using a plurality of methods such as method of limits, which is known to be a method of increasing a stimulus is detected or lowering it until no longer detected, thus correlated to a perception of temperature (column 1, lines 35-50). Gafni teaches using a skin temperature sensor (22) to communicate body surface temperature with the computer (figure 1, column 2, lines 50-54). Gafni doesn't teach directing an air stream onto the measurement area. However, Demand teaches a nerve sensitivity measuring apparatus, which uses pressurized fluid defined to be air (column 6, lines 29-32). It would have been obvious in view of Demand to use an apparatus that produces forced air in Gafni's method in order to remove possible

influences on perception of using solid object in contact with the test area.

Gafni further doesn't expressly teach determining the perceived temperature by detecting an environmental or organism parameter.

However, Laudadio teaches evaluating perceived temperature in relation to a controlled environmental temperature in order to diagnose neuropathy (column 1, lines 11-27) (column 6, line 50-column 7 line 19). It would have been obvious in view of Laudadio to evaluate results based on environmental or relative temperatures in Gafni modified by Demand in order to diagnose neuropathies.

- Regarding claims 2-3, Gafni teaches using two time periods during which the stimulus is present and is not present (column 4, lines 13-15). Gafni is silent as to moving the test element so it is presumed to be at a constant position. More important, there are only two alternative ways to position the device relative to the measurement point, one is constant and the other is variable. Absent any showing of unexpected benefit, it would have been obvious in the art to either position the device at a constant or variable spacing as such is taken to be well within the purview of choice in the art. Moreover, varying the distance would have been an obvious test method to try in order to test for nerve sensitivities.
- Regarding claim 5, Gafni uses a skin temperature sensor to send information back to the computer to influence the test protocol (column 2, lines 50-54).

- Regarding claim 8, Demand's air stream is variably adjustable or controllable such that an air velocity can be set and/or a volume stream can be adjusted to determine the perceived temperature (column 3, lines 44-60).
- Regarding claim 9, Demand's temperature display (82) would be capable of indicating a perceived temperature and feedback (52) of temperature sensor (50) would allow for determining of perceived temperature (Figure 1).
- Regarding claim 10, Demand's device has a portable probe, which would be capable of being moved varying distances from the target (Figure 1).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni modified by Demand and Laudadio as applied to claim 1 above, and further in view of Potter et al. (WO 03/000124).

- Regarding claim 4, Gafni and Demand don't teach using 3 superimposed light beams for determining the spacing. However, Potter, drawn to a measuring probe for a human body, teaches using two intersecting light beam for measuring the distance or spacing between the probe and the human body. Moreover, one in the art would have reasonably recognized and appreciated that more than two converging beams could be used effectively to calculate a measurement of a distance in space. For these reasons, it would have been obvious in the art to use two or three intersecting light beam in the modified device of Gafni in order to

accurately determine the distance between the device and human body and since one in the art would have recognized that whether two or three light beams are used, the same desired expected result of enabling one to obtain an accurate distance measurement would have been achieved.

7. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demand (US 4759712) in view of Gafni et al (US 5191896).

- Regarding claim 6, Demand teaches a device for determining thermal sensitivity of nerve sensitive tissue in which a means for producing an air stream, or pressurized fluid (i.e. air) source is connected to source line (92) (Figure 1, column 5, lines 8-10). It comprises a probe assembly (20) capable of directing air (figure 1) and a sensor (50) within tube (20) for measuring temperature of exiting air stream. Demand doesn't teach his system able to determine a perceived temperature at the measuring point. However, Gafni teaches a threshold sensitivity system wherein a probe is able to adapt temperatures until the stimulus was perceived and record perceived temperature (column 4, lines 39-49). It would have been obvious in view of Gafni to enable Demand's sensor to be able to determine perceived temperature in order to determine a patient's sensory threshold.
- Regarding claim 7, sensor (50) is capable of measuring air temperature (Figure 2).

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni modified by Demand and Laudadio as applied to claim 10 above, and further in view of Potter (WO 03/000124).

- Regarding claim 11, Gafni modified by Demand and Laudadio doesn't teach using light sources in the form of LEDs or laser diodes with intersecting beams at a predetermined spacing from the device. However, Potter teaches a diagnostic temperature probe with pair of LEDs (22) that are positioned to create mutually converging beams (24) at a predetermined distance (page 7, lines 4-7, Figure 1). It would have been obvious in light of Potter to use LEDs on Gafni modified by Demand and Laudadio's device in order to ensure a desired spacing between the device and the point being measured.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni and Demand, and Potter in view of May et al (US 2002/0108451).

- Gafni teaches a method of measuring sensory threshold which is used in the determination of sensory disorders in which a device is provided to measure thermal sensitivity using a plurality of methods such as method of limits, which is known to be a method of increasing a stimulus is detected or lowering it until no longer detected, thus correlated to a perception of temperature (column 1, lines 35-50). Gafni teaches using a skin temperature sensor (22) to communicate body surface temperature with the computer (figure 1, column 2, lines 50-54). Gafni doesn't teach

directing an air stream onto the measurement area. However, Demand teaches a nerve sensitivity measuring apparatus, which uses pressurized fluid defined to be air which inherently has humidity, temperature, spacing, and flow-rate parameters (column 6, lines 29-32). It would have been obvious in view of Demand to use an apparatus that produces forced air in Gafni's method in order to remove possible influences on perception of using solid object in contact with the test area.

- Further, Gafni teaches monitoring the temperature parameter with a display (82), but doesn't teach monitoring the other parameters. However, Potter, drawn to a measuring probe for a human body, teaches using two intersecting light beam for measuring the distance or spacing between the probe and the human body. May et al. teaches a gaseous mass flow measurement device which measures rate of flow, humidity, and temperature at the emission point [0102]. It would have been obvious in view of Potter and May to monitor all of the properties of Demand's gas in performing Gafni's method in order to keep all other variables constant.

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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